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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/188,051	11/06/98	SHIRLEY	B 5784-25

HM22/1012

CHIRON CORPORATION
INTELLECTUAL PROPERTY - R440
P.O. BOX 8097
EMERYVILLE, CA 94662-8097

EXAMINER

MOEZIE, F

ART UNIT

PAPER NUMBER

1653


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DATE MAILED:

10/12/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<i>file</i> Office Action Summary	Application No. 09/188,051	Applicant(s) Shirley et al	
	Examiner F. T. Moezie	Group Art Unit 1653	

☒ Responsive to communication(s) filed on Dec 13, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire one month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 29-84 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 29-84 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

STATUS OF CLAIMS

Claims 29-84 are currently pending in this application.

RESTRICTION REQUIREMENT

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 29-33, 44-48, drawn to compositions comprising an IGF-1 analog, classified in class 514, subclass depending on the structure of the analog.
- II. Claims 29-48, drawn to a composition comprising IGF-I, classified in class 514, subclass 12, for example.
- III. Claims 49-84, drawn to a method of using and /or preparing the compositions, classified in class 514, subclass depending on the structure of the active compound.

1. The inventions are distinct, each from the other because of the following reasons:

Inventions I or II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process of using the product as claimed can be practiced with another materially

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different product such as using histidine in the composition comprising an IGF-I or analogs thereof for imparting stability to the resulting composition .

Inventions I and II are distinct one from the other. Inventions are distinct because the active components are structurally different and would have to be made and used differently. Furthermore, the computer and library searches for the various active components are not coextensive. It would be an undue burden on the examiner to examine all of the inventions in one application.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

In accordance with the US practice, upon the allowance of a composition claim within the elected invention (e.g., Group I or II), the *Examiner will consider rejoinder* of method claims which are commensurate in scope to the allowed composition claims pursuant to MPEP 821.04 Rejoinder.

ELECTION OF SPECIES

This application contains claims directed to the following patentably distinct species of the claimed invention: (a) species of solubilizing compounds and (b) species of IGF-I analogs.

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Applicant is required under 35 U.S.C. 121 to elect a single disclosed specie for (a) a guanidine group containing compound and (b) an IGF-I analog (if analog elected) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention together with the election of the species (a) and (b) to be examined even though the requirement be traversed (37 CFR 1.143). Applicant is further required to clearly indicate the structure for the species and indicate claims reading on the elected species within the elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to F.T.Moezie whose telephone number is (703) 305-4508 or Mr. LOW (SPE) at 308-2923.

F.T. Moezie
MOEZIE, F.T.
SENIOR EXAMINER
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